REMARKS

Claims 1 and 8-10 stand rejected under 35 USC 112, first paragraph, as being non-enabling. This rejection is respectfully traversed.

The Examiner has maintained that the claims are non-enabling because there is not enough evidence of the effect of MAPG from representative strains of Mycobacterium in the record. A signed copy of Dr. Baxter declaration accompanies this amendment. As previously explained, Dr. Baxter's Declaration provides additional data showing that mycolyl arabinogalactin peptidoglycan (MAPG) from two representative strains of *Mycobacterium*, *Mycobacterium bovis* and *Mycobacterium tuberculosis*, prevents the development of type 1 diabetes and shows that a sub component of MAPG, arabinogalactin peptidoglycan (APG), prevents the development of Type 1 diabetes.

The Examiner further maintains that the phrase "a component of MAPG" encompasses components of unlimited or unspecified size and nature. This phrase has been deleted from the claims, rendering this part of the rejection moot.

Applicants have also added new claims 23-25, which claim one or more specific components of mycolyl-arabinogalactan-peptidoglycan (MAPG) selected from the group consisting of mycolic acids, peptidoglycan or arabinogalactan. These specific components are described on page 8, line 15 through page 9, line 4, of the specification.

Claims 1 and 10 stand rejected under 35 USC 102(a) as being anticipated by Stosic-Grujicic. This rejection is respectfully traversed.

The Examiner believes that the phrase "a component of MAPG" can include TDM and PPD, which are disclosed in Stosic-Grujicic. As recited above, the phrase "a component of MAPG" has been deleted from claim 1. Accordingly, this rejection should be withdrawn.

Claims 1 and 9 stand rejected under 35 USC 112, second paragraph, as being indefinite with regard to the limitation "a component of MAPG". Again, the phrase "a component of MAPG" has been deleted from claim 1. Accordingly, this rejection is now moot.

Claims 1 and 8-10 stand rejected under 35 USC 112, second paragraph, as being indefinite for the reasons recited in paragraph 14 of the office action dated December 7, 2004. Applicants have adopted all of the suggestions for overcoming these rejections provided by the Examiner. Accordingly, these rejections should be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing Attorney Docket No. 229752000600.

Dated: June 7, 2005

Respectfully submitted,

By _____

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Alan G Baxter.
Application No.	:	09/308,192
Filed	:	May 12, 1999
For	:	MYCOBACTERIUM CELL WALL COMPOSITIONS
Examiner	:	S Devi
Art Unit	:	1645
Docket No.	:	229752000600
Date	:	July 15, 2004

DECLARATION OF ALAN G. BAXTER, Ph.D.

Commissioner for Patents
Washington, D.C. 20231

The undersigned, Professor ALAN G. BAXTER, hereby declares:

1. At the time of filing of the above-identified application I was a Scientist at Centenary Institute of Cancer Medicine and Cell Biology.

2. We have shown that mycolyl arabinogalactin peptidoglycan (MAPG) from *Mycobacterium* prevents the development of Type I diabetes. This was confirmed in experiments performed in NOD/Lt mice in which two different strains of *Mycobacterium*, namely *Mycobacterium tuberculosis* and *Mycobacterium bovis,* were administered.

Female NOD/Lt mice spontaneously develop insulin-dependent diabetes mellitus (IDDM) by 35 weeks of age. The disease process involves a progressive preclinical phase of islet destruction, which commences at 4-6 weeks of age and concludes with the onset of clinical diabetes between 14 and 35 weeks of age.

These mice were intravenously injected with a single dose of MAPG of either heat killed *Mycobacterium tuberculosis* or heat killed *Mycobacterium bovis* BCG. Of the mice injected with the *Mycobacterium tuberculosis,* none developed diabetes (see Figure 1, Appendix A), while of those injected with *Mycobacterium bovis*, less than 50% developed diabetes.

These studies demonstrate that MAPG from different *Mycobacterium* prevent the development of diabetes.

Additional experiments were performed in which a sub-component of MAPG, namely arabinogalactan peptidoglycan (APG) was administered to NOD/Lt mice. APG is MAPG following the removal of mycolic acids. In these experiments, animals were injected with either 1mg of BCG, 0.8mg MAGP, 0.8mg AGP or normal saline (see Figure 2, Appendix A). These experiments demonstrate that in addition to MAPG from different *Mycobacterium* strains being able to prevent the development of diabetes, components of MAPG, such as APG, can also prevent the development of diabetes.

3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements, and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

ALAN G. BAXTER, Ph.D.

22/3/05.
Date